

K081107

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OCT 10 2008

510(k) Summary  
for the  
**Caspian Spinal System**

This 510(k) summary for the Caspian Spinal System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

**1. Submitter :**

K2M, Inc.  
751 Miller Drive SE,  
Suite F1  
Leesburg, VA 20175

**Contact Person :**

Richard W. Woods  
K2M, Inc.  
751 Miller Drive SE, Suite F1  
Leesburg, VA 20175  
Telephone: 703-777-3155

Date Prepared: 10/10/08

**2. Tradename:**

Caspian Spinal System

**Common Name:**

Spinal Fixation System

**Classification Name:**

Spinal Interlaminar Fixation Orthosis (21CFR 888.3050)

**Device Product Code:**

KWP

**Regulatory Class:**

Class II

**3. Predicate or legally marketed devices which are substantially equivalent :**

- Synthes Starlock/ Cervifix
- Interpore Mini VLS/ Altius
- DePuy Mountaineer
- Spinal Concepts Octafix

**4. Description of the device:**

The Caspian Spinal System is a top-loading, multiple component, posterior (cervical-thoracic) spinal fixation system which consists of pedicle screws, rods, locking set screws, hooks, and rod connectors.

**Materials:** The devices are manufactured from Ti6Al4V per ASTM and ISO standards.

**Function:** The system functions as an adjunct to fusion to provide immobilization and stabilization of spinal segments of the cervical and thoracic (T1-T3) spine.

**5. Intended Use:**

The Caspian Spinal System is indicated for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Revision of previous cervical spine surgery
- Tumors

**Hooks and Rods**—The rod and hook components are also intended to provide stabilization as an adjunct to fusion when used with autogenous bone graft or allograft following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

**Rods and Pedicle Screws**—The rods and screws are intended to provide stabilization as an adjunct to fusion when used with autogenous bone graft or allograft following reduction of fracture/dislocation or trauma in the upper thoracic spine (T1-T3). The use of these screws is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in or treat conditions involving the cervical spine.

**6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :**

The Caspian Spinal System is considered substantially equivalent to other legally marketed devices.

They are similar in design, material, and indications for use and are expected to be equivalent in safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 10 2008

K2M, Inc.  
c/o Mr. Richard W. Woods  
751 Miller Drive SE, Suite F1  
Leesburg, Virginia 20175

Re: K081107

Trade/Device Name: Caspian Spinal System  
Regulation Number: 21 CFR 888.3050  
Regulation Name: Spinal Interlaminar Fixation Orthosis  
Regulatory Class: Class II  
Product Code: KWP  
Dated: October 09, 2008  
Received: October 10, 2008

Dear Mr. Woods:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Richard W. Woods

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: Caspian Spinal System

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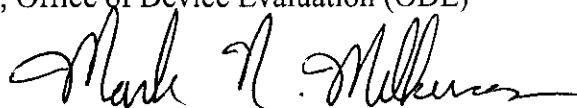
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number K081107